


## Vitamin D Control

<b>LOT</b>	Expiry date 
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### Intended Use

The Vitamin D control is intended for use as quality controls for the Vitamin D assay. **For in vitro diagnostic use only.**

### Summary

The Vitamin D control is a set of two control levels. These two levels are to be used with the Vitamin D assay, which is a direct particle-enhanced assay for the quantification of vitamin D in human serum and plasma.

### Reagents – Working solutions

#### Reactive components

- Human serum and additives

#### Non-reactive components

- Sodium azide (NaN<sub>3</sub>) < 0.1 %

The Vitamin D Control set is a two-level set that is supplied in liquid form (2x3 ml). The control set is manufactured from human serum. The concentrations are expressed in ng/mL.

### Target values and ranges

Lot specific target values and ranges are stated in the Certificate of Analysis. Results should be within the defined ranges. Each laboratory should establish corrective measures to be taken if values fall outside the range.

### Precautions

- For *in vitro* diagnostic use only. Rx Only.
- Exercise the normal precautions for handling all laboratory reagents. Each donor unit of serum in the preparation of these materials were tested by approved methods and found negative Hepatitis B surface antigen (HBsAg), and Hepatitis C Virus antibody (HCV). Because no method can offer complete assurance as to the absence of infectious agents, this material and all samples should be handled as though capable of transmitting.
- Additional safety information concerning storage and handling of this product is provided within the MSDS for this product.
- Avoid contact with skin and eyes.
- Contains sodium azide, which may react with lead or copper plumbing to form explosive compounds. Flush drains with copious amounts of water when disposing of this reagent.

### Handling, Storage and Stability

The Vitamin D control set is supplied in liquid form. Mix carefully before each use. Avoid the formation of bubbles.

Store at 2 to 8 °C. **DO NOT FREEZE.**

Note: Store control tightly capped when not in use.

### Stability

Unopened vial: stability is up to the expiration date on label when stored at 2 to 8 °C.

### Materials provided

The Vitamin D control set consists of 2 liquid vials.

### Materials required but not provided

- Vitamin D assay reagents cod. R000000005
- Vitamin D calibrator set cod. R000000006
- General laboratory equipment

### Assay

Prepare control 1 and 2 as stated in the Handling section. Take care to avoid the formation of bubbles. The control testing intervals should be adapted to each laboratory's individual requirements. Follow the applicable government regulations and local guidelines for quality control.

Note: The Vitamin D assay control kit cod. R000000007 is recommended to be used as daily quality control.

### Limitations

As any particle – enhanced assay, Vitamin D Assay runs should be followed with appropriate wash steps. Please consult instrument manuals for further information.

Vitamin D reagent, calibrator and control should be stored at 2-8 °C. **DON NOT FREEZE**

### Disposal of reagent








Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

**The product is in conformity with D.L: 8 September 2000, no. 332 "Actuation of the directive 98/79/EC regarding in vitro medical diagnostic devices".**

### Assigned Values

Control	Target	Range
Low – level 1		
High – level 2		

### Symbols on labels and packaging

	In vitro diagnostic medical device
	Catalog Number
	Lot number
	Manufacturer
	Expiry date
	Temperature limitation
	Consult Instructions for use

### History Revision

Revision	Description
08/2018	First Emission
10/2023	General reorganisation

